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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/437,912	11/09/1999	KEITH R. MCCRAE	6056-257	8628

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EXAMINER

ROBINSON, HOPE A

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 09/04/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/437,912

Applicant(s)

MCCRAE, KEITH R.

Examiner

Hope A. Robinson

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1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 8, 9, 16, 19, 22 and 30-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 16, 19, 22 and 36-49 is/are allowed.
- 6) ☐ Claim(s) 1-4, 8, 9 and 30-32, 34, 35 is/are rejected.
- 7) ☐ Claim(s) 33 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

1. Applicant's response to the Office Action mailed March 25, 2003 in Paper No. 23 on June 16, 2003 is acknowledged.
2. Claims 34 and 35 have been amended. Claims 1-4, 8-9, 16, 19, 22, 30-49 are pending.
3. The following grounds of rejection are or remain applicable:

Specification

4. The specification is objected to because on pages 10-11 the trademark Matrigel is recited and is not completely capitalized, for example "MATRIGEL". Note that on page 11 the trademark symbol is missing. (see page 10, line 28 and page 11, line 30).
Correction is required. Additionally, the trademarks are not accompanied by generic terminology sufficient to describe the referenced products.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4, 8-9 and 30-32 remain rejected under 35 U.S.C. 102(b) as being anticipated by Ferreira et al. (WO 97/05258, February 13, 1997) based on a formula wherein X is any amino acid, X₁ is a fragment thereof containing at least one amino acid and X₂ is zero amino acids.

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Ferreira disclose peptides for use in diagnostic and therapeutic methods. Ferreira disclose the sequence contained in claim 1 in SEQ ID NO: 113 of the reference, where the sequence is Glu-Ala-Pro-His-Lys-Phe-Lys-Asn-Val which means that X is Phe (as in claims 3 and 4), X₁ is a fragment and X₂ is two amino acids. The sequence disclosed by Ferreira also meets the limitation of claim 2, which requires X₁ and X₂ to be from zero to six amino acids or zero amino acids. Thus, the limitations of the claims are met by this reference.

6. Claims 1 and 35 remain rejected under 35 U.S.C. 102(b) as being anticipated by (FARH) HOECHST JAPAN, Accession Number AAR75186, JP07082172-A, 1995, based on a formula wherein X is any amino acid, X₁ is a fragment thereof containing at least one amino acid and X₂ is zero amino acids.

The reference teach a sequence that encompasses the basic sequence "Gly-His-Lys-X-Lys". In addition, the reference teaches a compound that is a 100% identical to the compound as set forth in SEQ ID NO: 9 of the instant application. Although the reference sequence is longer the claims are anticipated because the claims recite the open language "having" "comprising". Thus, the limitations of the claims are met by the reference.

7. Claim 34 remain rejected under 35 U.S.C. 102(b) as being anticipated by (SUMU) SUMITOMO SEIYAKU KK, Accession Number AAW07625, JP08208692-A, 1996.

The reference teaches a compound that is a 100% identical to the compound as set forth in SEQ ID NO: 8 of the instant application. Although the reference sequence is longer the claim is anticipated because the claim recites the open language "having". Thus, the limitations of the claim are met by the reference.

8. Applicant's arguments filed June 16, 2003 were not sufficient to overcome the rejection of record under 35 U.S.C. 102. Regarding the rejection under 35 U.S.C. 102, applicant contends that "the examiner's interpretation of the claimed language "N-terminal truncation fragment...containing at least one amino acid" is against of the spirit and intended scope of the claimed language". Applicant further states that "N-terminal truncation" means removing one or more contiguous amino acids beginning from the N-terminus of SEQ ID NO: 1" (see pages 3-4 of the response). However, these statements are not accurate. The specification on page 9 states that "By N-terminal truncation fragment with respect to an amino acid sequence is meant a fragment obtained from a parent sequence by removing one or more amino acids from the N-terminus thereof" and the same language is used to describe the C-terminus truncation fragment. Therefore, the language is very clear as stated in the disclosure that one or more amino acids can be removed and there is no statements made that it has to be contiguous amino acids or beginning from the N-terminus. It simply states "removing one or more amino acids from the N-terminus". Thus, the interpretation of the claim is based on the plain language in the specification. In addition, the claim is directed to an "N-terminal truncation fragment". The response again points to Table 1 and Table 2 which are two ways of interpreting the claims, however, the claims can also be interpreted as set forth in the office action based on the present claim language, thus the cited prior art remains relevant and applicant's arguments are not persuasive. Moreover the tables were addressed in detail in Paper No. 21.

Note that the rejections of record remain over claims 34 and 35 although amended. The claims have been amended to recite "consisting essentially of". This language according to the MPEP occupies a middle ground between closed claims that are written in a consisting of format and fully open claims that are drafted in a comprising format. The MPEP also state that absent a clear indication in the specification or claims of what the basic and novel characteristics actually

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are, "consisting essentially of" will be construed as equivalent to "comprising" (see MPEP 211.03). Thus the rejections of record remains. The arguments presented on pages 3-10 have been addressed above.

Conclusion

9. Applicant's amendment necessitated the new/modified ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

10. Claims 16, 19, 22 and 36-49 are free of the art. Claim 33 is objected to as depending from a rejected based claim, however, if rewritten in independent format would be allowable.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope Robinson whose telephone number is (703) 308-6231. The examiner can normally be reached on Monday-Friday from 9:00 am to 5:30 pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S.F. Low, can be reached at (703) 308-2923.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-4242. Please affix the examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope Robinson, MS

Patent Examiner

Christopher S. F. Low

**CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600**